

Message

From: Luke, April [Luke.April@epa.gov]
Sent: 10/17/2016 4:34:02 PM
To: Lehmann, Geniece [Lehmann.Geniece@epa.gov]
CC: Macaulay, Laura [Macaulay.Laura@epa.gov]; Rutigliano, Marian [Rutigliano.Marian@epa.gov]; Arzuaga, Xabier [Arzuaga.Xabier@epa.gov]
Subject: RE: materials for reviewing the oral exposure study quality protocol
Attachments: Draft Protocol-Evaluation of Oral Exposure Quality_PCBs_XA_AL comments.docx

Hi Geniece,

Ex. 5 Deliberative Process (DP)

Let me know if I can clarify any comments I made.

Thanks for putting this together.

April

From: Arzuaga, Xabier
Sent: Tuesday, October 04, 2016 11:07 AM
To: Lehmann, Geniece <Lehmann.Geniece@epa.gov>
Cc: Macaulay, Laura <Macaulay.Laura@epa.gov>; Rutigliano, Marian <Rutigliano.Marian@epa.gov>; Luke, April <Luke.April@epa.gov>
Subject: RE: materials for reviewing the oral exposure study quality protocol

Hi Geniece,

Thank you very much for the opportunity to comment on the protocol and I apologize for my delayed response. I'm attaching my comments and observations to the protocol. I used the table provided in the word file to enter 3 examples. My examples are at the end of the file. I hope that's OK.

For now, I believe we should focus on various reporting categories. I believe that adding interpretation on the impact of the type of vehicle or exposure regimen would require additional analysis for each type of endpoint within the health hazards. Please let me know if you have any questions or would like to discuss further. Cheers!

Xabier

From: Lehmann, Geniece
Sent: Monday, October 03, 2016 2:17 PM
To: Rutigliano, Marian <Rutigliano.Marian@epa.gov>; Arzuaga, Xabier <Arzuaga.Xabier@epa.gov>; Luke, April <Luke.April@epa.gov>
Cc: Macaulay, Laura <Macaulay.Laura@epa.gov>
Subject: FW: materials for reviewing the oral exposure study quality protocol

Hi Marian, Xabier, & April,

Please see the instructions below that ICF prepared for their subcontractors. Since I can't seem to get assignment information to people in an effective way, I'm just going to let ICF provide the assignments and piggyback off their efforts. So, you can consider the instructions in the email below to apply to you as well (except you should send your evaluation and comments to me instead of sending them to Joanne).

Thanks,
Geniece

Geniece M. Lehmann, Ph.D.
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From: Trgovcich, Joanne [<mailto:Joanne.Trgovcich@icf.com>]
Sent: Monday, October 03, 2016 1:38 PM
To: Michal Toborek <MToborek@med.miami.edu>; Aileen Keating (akeating@iastate.edu) <akeating@iastate.edu>; MaryJane Selgrade <selgrade@bellsouth.net>; larry-robertson@uiowa.edu; Pamela Lein <pjlein@ucdavis.edu>
Cc: Lehmann, Geniece <Lehmann.Geniece@epa.gov>; Burch, Dave <dave.burch@icf.com>
Subject: materials for reviewing the oral exposure study quality protocol

Hello Michal, Aileen, MaryJane, Larry and Pam,
As a follow up to our team meeting today, I am sending you the "Draft Protocol – Evaluation of Oral Exposure Quality PCBs" and the "Evaluation of Oral Exposure Quality PCBs documentation table". Instructions for testing the protocol are below (these are copied from the 8/29/16 Team Meeting Minutes). Please review the protocol and the documentation table, test the protocol on 2-3 studies in your inventory, and provide feedback at our next Team Meeting (October 17th). If you will not be able to attend this meeting, please email me your evaluation and comments. You can find these documents and additional supporting material on the Shared Folder (PCB Assessment Team > Study Quality Evaluation Protocol Development > Animal Tox – Oral Exposure Protocol).
Let me know if you have any questions.
Best regards,
Joanne

STUDY QUALITY EVALUATION PROTOCOLS – ANIMAL TOXICOLOGY STUDIES

- We discussed some of the questions raised during team review of our draft protocol for evaluating the quality of oral exposure methods used in animal toxicology studies of PCBs.
- A new draft has been developed for review by PCB team toxicologists. Materials can be found in PCB Assessment Team > Study Quality Evaluation Protocol Development > Animal Tox – Oral Exposure Protocol.
 - [Draft Protocol-Evaluation of Oral Exposure Quality PCBs.docx](#)
 - Review and provide comments on this document (due 10/3/2016)
 - [Evaluation of Oral Exposure Quality PCBs documentation table.xlsx](#)
 - Complete the following exercise (due 10/3/2016):
 - Choose 2-3 studies from your literature inventory
 - Following the protocol described in [Draft Protocol-Evaluation of Oral Exposure Quality PCBs.docx](#), evaluate the oral exposure methods used in those studies and fill in the table in [Evaluation of Oral Exposure Quality PCBs documentation table.xlsx](#)

- Use your experience evaluating those 2-3 studies to complete your review and to provide further feedback on Draft Protocol-Evaluation of Oral Exposure Quality PCBs.docx
- The next step is to have the protocol reviewed by the IRIS general toxicology and systematic review workgroups.
- Once that review is complete and revisions have been made, PCB team toxicologists will be asked to test the protocol on 6-10 studies, and a meeting will be held to review and compare the resulting study quality evaluations, reaching consensus on areas of disagreement, and making revisions to the protocol as necessary.
- The tested protocol will be reviewed by the IRIS general toxicology workgroup.
- Once that review is complete and revisions have been made, the protocol will be considered ready for use.

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